



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific IVT  
c/o Ms. Renuka S. Krishnan  
Principal Specialist, Regulatory Affairs  
3574 Ruffin Road  
San Diego, CA 92123

Re: K051254  
Peripheral Cutting Balloon™  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II (two)  
Product Code: PNO  
Dated: May 13, 2005  
Received: May 16, 2005

Dear Ms. Krishnan:

This letter corrects our substantially equivalent letter of June 22, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Misti L. Malone -S**

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K051254

Device Name: Peripheral Cutting Balloon™

### Indications For Use:

The Peripheral Cutting Balloon™ catheters are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Prescription Use: Yes  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: No  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Doranne R. Vachon  
(Division Sign-Off)  
Division of Cardiovascular Devices

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**510(k) SUMMARY**

<b>Submitter's Name and Address</b>	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
<b>Contact Person</b>	Renuka Krishnan Principal Specialist, Regulatory Affairs (858)503-1815
<b>Common or Usual Name</b>	PTA catheter
<b>Product Code</b>	LIT
<b>Classification</b>	Class II
<b>Proprietary Names</b>	<ul style="list-style-type: none"><li>• 1 cm Peripheral Cutting Balloon™</li><li>• 2 cm Peripheral Cutting Balloon™</li><li>• small Peripheral Cutting Balloon™ Over-the -wire delivery system</li><li>• small Peripheral Cutting Balloon™ Monorail delivery system</li></ul>

**Predicate Devices**

Boston Scientific Ultra-Thin Diamond Balloon Dilatation Catheter, K960501  
Polarcath™ Peripheral Balloon Catheter system, K030742  
CVSi Peripheral Balloon Catheter system, K022061

**Device Description**

The Peripheral Cutting Balloon™ (PCB) has the features of a conventional angioplasty catheter, with advanced microsurgical capabilities. The PCB features a non-compliant balloon with three or four atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The device is inserted over a guidewire and delivered to the target lesion. Upon inflation, the atherotomes score the plaque as the balloon expands and pushes the plaque radially. The scores serve as notches for stress concentration and allow dilatation at lower pressures, minimizing barotrauma.

Three of the PCB devices (1 cm, 2 cm and sPCB OTW) are offered in Over-the-Wire delivery configuration, the sPCB is also available in Monorail configuration. The OTW devices are attached to a Y-connector at one end, the sPCB MR is attached to a female luer. The OTW catheters feature a co-axial shaft consisting of an inflation lumen and a guidewire lumen; the sPCB MR features a proximal shaft using a single lumen hypotube, which is attached to a coaxial distal section consisting of an inflation and guidewire lumen. The guidewire exit port for the sPCB MR is 24 cm from the catheter tip.

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Table 1. Model Numbers, 1 cm and 2 cm PCB

Device	Nom. Diameter	Catheter Length		
		50 cms	90 cms	135 cms
1 cm PCB	5.0 mm	BP505010	BP905010	BP1355010
	5.5 mm	BP505510	BP905510	BP1355510
	6.0 mm	BP506010	BP906010	BP1356010
	7.0 mm	BP507010	BP907010	BP1357010
	8.0 mm	BP508010	BP908010	BP1358010
2 cm PCB	5.0 mm	PCB502050	PCB502090	PCB5020135
	6.0 mm	PCB602050	PCB602090	PCB6020135
	7.0 mm	PCB702050	PCB702090	PCB7020135
	8.0 mm	PCB802050	PCB802090	PCB8020135

Table 2. Model Numbers, sPCB\*

Nom. Diameter (mm)	Over-the-Wire	Monorail
2.00	PCBO2015140	PCBM2015140
2.50	PCBO2515140	PCBM2515140
3.00	PCBO3015140	PCBM3015140
3.50	PCBO3515140	PCBM3515140
4.00	PCBO4015140	PCBM4015140

\* Catheter length: 140 cm; blade length: 1.5 cm.

Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. The sPCB devices are coated with Bioslide at the distal section, the 1 cm and 2 cm PCB are coated with MDX 4-4159.

The Rated Burst Pressure (RBP) for all devices is 10 atm. The devices are available in nominal balloon diameters from 2.0 mm to 8.0 mm and blade lengths of 1 cm to 2 cm (Tables 1-2).

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#### **Intended Use**

The Peripheral Cutting Balloon catheters are recommended for Percutaneous Transluminal Angioplasty of obstructive lesions in synthetic or native arteriovenous dialysis fistulae.

#### **Substantial Equivalence**

The Peripheral Cutting Balloon catheters will incorporate a substantially equivalent design, fundamental technology and intended use as those featured in predicate devices.

#### **Performance Testing**

Bench testing and biocompatibility testing support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

#### **Conclusion**

The Peripheral Cutting Balloon catheters have been shown to be Substantially Equivalent to the predicate devices.